8.0 QUALITY OF DATA REVIEWED

8.1 Extent of Adherence to GLP Guidelines

Ideally, all data supporting the validity of a test method should be obtained and reported in accordance with GLP guidelines, which are nationally and internationally recognized rules designed to produce high-quality laboratory records. GLPs provide a standardized approach to the reporting and archiving of laboratory data and records, and information about the test protocol, to ensure the integrity, reliability, and accountability of a study (U.S. EPA, 2001, 2002; FDA, 2002).

Based on the information provided in the reports included in this BRD, none of the *in vitro* AR TA studies were conducted in compliance with national or international GLP guidelines.

8.2 Assessment of Data Quality

Formal assessments of data quality, such as quality assurance audits, generally involve a systematic and critical comparison of the data provided in a study report or published paper to the laboratory records generated during a study. No attempt was made to formally assess the quality of the *in vitro* AR TA data included in this document. The published and submitted data on the TA of AR-inducible genes were limited, in most reports, to the response of the test substance relative to a reference androgen and, to a lesser extent, EC_{50} and IC_{50} values, and rates of enzyme activity. Auditing these reported data and values would require obtaining the original data for each study, which is not readily available.

An informal assessment of the *in vitro* AR TA publications revealed certain limitations that complicate interpretation of the reported AR TA data (**Appendix D**):

- *Various formats used to present the data*: The data were reported in a variety of formats (e.g., fold induction or increase, relative potency ratios, relative agonistic activity, EC_{50} and IC_{50} values, and rates of enzyme activity). The values reported were, as a rule, obtained from different protocols, against different standards. These factors precluded a quantitative analysis of results obtained by different laboratories for the same test substance.

- *Large number of substances tested in only one laboratory*: Less than half of the substances included in this BRD have been tested in more than one laboratory. Therefore, the inter-laboratory reproducibility of the results for these substances is not known.
- *Large number of substances without information regarding within-laboratory reproducibility*: There is often no information in the publications as to the number of replicates or repeat experiments performed. Therefore, the within-laboratory repeatability of many of the test results is not known.
- *Insufficient methodology information:* A number of publications contained limited details about the test methods, cells, and vectors used. In some cases, publications reported that the methods were "performed as previously described," and in many of these cases the cited publication either referenced another publication for experimental details, or was not relevant to the particular protocol. At times, following this trail of references made it difficult to determine the actual protocol used to produce the data reported in the specific publication being abstracted.
- *Inconsistent nomenclature of test substances:* Most publications did not provide CASRNs for the substances tested, or used a unique chemical nomenclature, which in some cases made unequivocal identification of the test chemical difficult.

8.3 Quality Control Audit

A quality control (QC) audit was conducted of the *in vitro* AR TA database provided in **Appendix D**. In conducting this audit, data input into the database was checked against the original sources and corrected if an entry error had been made.